DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 5, 2015

Shanghai Microport Medical (group) Co., Ltd
Erika Huffman
Medical Research Manager, Regulatory
4050 Olson Memorial Highway,
Minneapolis, Minnesota 55422

Re: K143160
Trade/Device Name: FOXTROT NC PTCA Balloon Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: February 2, 2015
Received: February 5, 2015

Dear Erika Huffman,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143160

Device Name
FOXTROT™ NC PTCA Balloon Catheter

Indications for Use *(Describe)*

The FOXTROT™ NC PTCA Balloon Catheters are indicated for the balloon catheter dilatation of the stenotic portion of a native coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. FOXTROT™ NC PTCA Balloon Catheters are also indicated for the post-delivery expansion of balloon expandable stents.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5.0 510(k) Summary

Submitter:	Shanghai MicroPort Medical (Group) Co., Ltd 501 Newton Road ZJ Hi-Tech Park Shanghai, China 201203
Contact Person:	Erika Huffman Medical Research Manager, Regulatory NAMSA 4050 Olson Memorial Hwy. Suite 450 Minneapolis, MN 55422 USA Phone: +1-763-588-9857 Fax: +1-763-287-3836 ehuffman@namsa.com
Date Prepared:	October 30, 2014
Trade Name:	FOXTROT™ NC PTCA Balloon Catheter
Common Name:	Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Classification:	Class II, 21 CFR Part 870.5100
Product Code:	LOX
Predicate Device:	K121667 - NC Quantum Apex™ Monorail PTCA Dilatation Catheter (Boston Scientific) *This predicate device has not been subject to a design-related recall.*
Reference Devices:	• K111544 - Glider™ PTCA Balloon Catheter (TriReme Medical, Inc.) • K123264 - DK-PTCA Balloon Catheter (Intuit Medical, LLC)
Device Description:	The FOXTROT NC PTCA Balloon Catheter device is a sterile, single-use, rapid exchange percutaneous transluminal coronary angioplasty catheter. The design is an integrated shaft system with a balloon near the distal tip. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. Two radiopaque markers aid in positioning the balloon catheter under fluoroscopy during the procedure. The distal portion of the shaft is coated with a hydrophilic coating to provide lubrication. The effective length of the FOXTROT NC device is 145 cm and it is compatible with a 0.014" guide wire. The FOXTROT NC PTCA balloon catheter

	is available with balloon diameters of 2.5-4.0 mm and balloon lengths of 10 mm and 15 mm.
Indications for Use:	The FOXTROT™ NC PTCA Balloon Catheters are indicated for the balloon catheter dilatation of the stenotic portion of a native coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. FOXTROT™ NC PTCA Balloon Catheters are also indicated for the post-delivery expansion of balloon expandable stents.
Comparison with Predicate Device:	The FOXTROT NC PTCA Balloon Catheter is similar to the NC Quantum Apex Monorail PTCA Dilatation Catheter in the following ways: • Each of the devices are intended to be used for dilatation of stenoses to improve myocardial perfusion. • Each of the devices are intended to be used for post-delivery expansion of balloon expandable stents. • Each of the devices is compatible with a 0.14" (0.36 mm) guide wire. • Each of the devices is designed to be a rapid exchange catheter. • Each of the devices is provided sterile. • Each of the devices is intended to be single use. • Each device has two platinum-iridium radiopaque marker bands to aid in positioning the balloon during a procedure. • Each device has markers along the proximal shaft to indicate the depth of catheter insertion. • Each of the devices has a hydrophilic coating. • Each of the devices is available in balloon diameters ranging from 2.5 mm to 3.5 mm (in 0.25 mm increments). Each of the devices also has an available 4.0 mm balloon diameter. • Each of the devices has an available 15 mm balloon length. • Each of the devices has a nominal balloon pressure of 12.0 atm. • Each of the devices has a rated burst pressure of 20 atm for 2.5-4.0 mm balloon diameters. The following technological differences exist between the subject and predicate devices: • Effective length • Recommended guide catheter • Available balloon lengths

Performance Data:	Biocompatibility Testing The biocompatibility evaluation for the FOXTROT NC device was conducted in accordance with current standards and included the following tests: • Cytotoxicity • Sensitization • Irritation/Intracutaneous Reactivity • Systemic Toxicity • Pyrogenicity • Hemolysis • Complement Activation • Partial Thromboplastin Time • Thrombogenicity Bench Testing Mechanical testing was performed per the *FDA Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters* (September 2010) on both the subject device and the predicate device. The tests included the following: • Dimensional Verification • Balloon Preparation, Deployment and Retraction • Balloon Rated Burst Pressure • Balloon Fatigue • Balloon Compliance • Balloon Inflation and Deflation Time • Catheter Bond Strength • Tip Pull Test • Flexibility and Kink Test • Torque Strength • Radiopacity • Coating Integrity • Particulate Evaluation • Balloon Rated Burst Pressure (in Stent) • Balloon Fatigue (in Stent) • Corrosion Resistance • Smoothness of the guidewire lumen
Conclusion:	The data provided support the safety of the FOXTROT NC device and the mechanical testing results demonstrate that the device should perform as intended in the specified use conditions. Non-clinical tests demonstrate that the FOXTROT NC device is substantially equivalent to the predicate device which is currently marketed for the same intended use.